PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 12486620	FOR FURTHER ACTION See Form PCT/IPEA/416	
International application No. PCT/AU2004/001129	International filing date *(day/month/year)* 20 August 2004	Priority date *(day/month/year)* 21 August 2003

International Patent Classification (IPC) or national classification and IPC

Int. Cl.

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A61K 39/00 (2006.01) *C12N 15/12* (2006.01)

Applicant

VIRAX DEVELOPMENT PTY LTD et al

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 4 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
   a. [X] *(sent to the applicant and to the International Bureau)* a total of **6** sheets, as follows:
      - [X] sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
      - [ ] sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.

   b. [ ] *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or table related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).
4. This report contains indications relating to the following items:

[X]	Box No. I	Basis of the report
[ ]	Box No. II	Priority
[ ]	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
[ ]	Box No. IV	Lack of unity of invention
[X]	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
[ ]	Box No. VI	Certain documents cited
[ ]	Box No. VII	Certain defects in the international application
[X]	Box No. VIII	Certain observations on the international application

Date of submission of the demand	Date of completion of this report
17 June 2005	01 January 2006
Name and mailing address of the IPEA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustralia.gov.au Facsimile No. (02) 6285 3929	Authorized Officer **ANDREW ACHILLEOS** Telephone No. (02) 6283 2280

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/AU2004/001129

Box No. I Basis of the report

1. With regard to the **language**, this report is based on:

[X] The international application in the language in which it was filed

[ ] A translation of the international application into , which is the language of a translation furnished for the purposes of:

[ ] international search (under Rules 12.3(a) and 23.1 (b))

[ ] publication of the international application (under Rule 12.4(a))

[ ] international preliminary examination (Rules 55.2(a) and/or 55.3(a))

2. With regard to the **elements** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

[ ] the international application as originally filed/furnished

[X] the description:

pages **1-48** as originally filed/furnished
pages* received by this Authority on with the letter of
pages* received by this Authority on with the letter of

[ ] the claims:

pages as originally filed/furnished
pages* as amended (together with any statement) under Article 19
pages* **49-54** received by this Authority on **17 June 2005** with the letter of **17 June 2005**
pages* received by this Authority on with the letter of

[X] the drawings:

pages **1/15-15/15** as originally filed/furnished
pages* received by this Authority on with the letter of
pages* received by this Authority on with the letter of

[ ] a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.

3. [ ] The amendments have resulted in the cancellation of:

[ ] the description, pages
[ ] the claims, Nos.
[ ] the drawings, sheets/figs
[ ] the sequence listing *(specify)*:
[ ] any table(s) related to the sequence listing *(specify)*:

4. [ ] This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

[ ] the description, pages
[ ] the claims, Nos.
[ ] the drawings, sheets/figs
[ ] the sequence listing *(specify)*:
[ ] any table(s) related to the sequence listing *(specify)*:

* *If item 4 applies, some or all of those sheets may be marked "superseded."*

Box No. V **Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Claims	**1-19, 22-47**	**YES**
	Claims	**20, 21**	**NO**
Inventive step (IS)	Claims	**1-19, 22-47**	**YES**
	Claims	**20, 21**	**NO**
Industrial applicability (IA)	Claims	**1-47**	**YES**
	Claims		**NO**

2. Citations and explanations (Rule 70.7)

The following documents were cited in the ISR:

D2=WO 1998/046769

D3=Fong L *et al*, *The Journal of Immunology*, 1997, 159(7): 3113-17.

Your application defines a genetic vaccine construct for prostate cancer comprising an avipox viral vector which does not productively infect a subject and expresses a xenogeneic prostate specific polypeptide. Your claims 1-19 and 22-47 are novel and inventive over the prior art cited in the ISR. The prior art discloses genetic vaccines comprised of an avipox viral vector and expressing human prostate specific peptides and genetic vaccines comprised of vaccinia viral vectors and expressing xenogeneic prostate specific peptides. However, a genetic vaccine construct for prostate cancer comprising an avipox viral vector which does not productively infect a subject and expresses a xenogeneic prostate specific polypeptide is not disclosed.

Novelty and Inventive Step

Claims 20 and 21

Your claim 20 defines antibodies to the xenogeneic expression products of the genetic vaccines. The expression products are known peptides from the surface of prostate cancer cells, for example, mouse PAP (refer to D3 at page 4 lines 5-6 of your description). Also, D2 and D3 disclose rat PAP.

While antibodies to a known protein may not have been raised before, this practice is so common in the art that no inventive step can be recognised for a claim defining antibodies to a known protein. Therefore, your claim 20 involves no inventive step.

In a similar vein, your claim 21 defines probes to the nucleotide sequence of the genetic vaccine construct (refer to clarity objection in Box VIII). This nucleotide sequence expresses xenogeneic prostate specific polypeptides. These polypeptides are known proteins (D2 and D3, mouse and rat PAP), therefore their nucleotide sequence is also known. Preparing probes to the nucleotide sequences of known proteins is so common in the art that no inventive step can be recognised. Therefore, your claim 21 involves no inventive step.

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

1. Claim 21 is not clear because it defines a nucleic acid probe that specifically recognises the defined "genetic vaccine construct" and is not limited to recognising the nucleotide sequence of the genetic vaccine construct. The genetic vaccine construct comprises a viral vector and a nucleotide sequence that expresses a xenogenenic prostate specific polypeptide. A nucleic acid probe will only be able to hybridise to the nucleotide sequence of the viral vector and not to the viral vector coat; as the viral vector coat is made up of protein.

Replacement sheets

CLAIMS

1. A genetic vaccine construct comprising an avipox virus vector which incorporates and, on administration to a subject, expresses in a cell of said subject, a sequence of nucleotides encoding a xenogeneic prostate specific polypeptide or a derivative or analogue thereof, wherein said avipox virus vector does not productively infect said subject.

2. A genetic vaccine construct comprising an avipox virus vector which incorporates and, on administration to a subject, expresses in a cell of said subject, a sequence of nucleotides encoding a xenogeneic prostate specific polypeptide or a derivative or analogue thereof, and a sequence of nucleotides encoding an immunostimulatory polypeptide, wherein said avipox virus vector does not productively infect said subject.

3. The genetic vaccine construct of claim 1 or 2, wherein the prostate specific polypeptide is prostatic acid phosphatase or a derivative or analogue thereof.

4. The genetic vaccine construct of any one of claims 1 to 3, wherein the subject is a human subject.

5. The genetic vaccine construct of claim 4, wherein the xenogeneic prostate specific polypeptide is rodent prostatic acid phosphatase.

6. The genetic vaccine construct of claim 5, wherein the rodent prostatic acid phosphatase is rat prostatic acid phosphatase.

7. The genetic vaccine construct of claim 2, wherein the immunostimulatory polypeptide is a cytokine.

8. The genetic vaccine construct of claim 7, wherein the cytokine is one or more of IL-2, IL-12, TNFα, IFNγ, IL-6, IL-4, IL-7 or GM-CSF.

9. The genetic vaccine construct of claim 8, wherein the cytokine is one or more of

IL-2, IFNγ or IL-12.

10. The genetic vaccine construct of claim 9, wherein the cytokine is IL-2.

11. The genetic vaccine construct of any one of claims 1 to 10, wherein the avipox virus vector is a fowlpox virus vector.

12. A composition comprising the genetic vaccine construct according to any one of claims 1 to 11.

13. A composition consisting essentially of the genetic vaccine construct according to any one of claims 1 to 11.

14. The composition of claim 12 or 13, wherein expression products of said genetic vaccine construct stimulate a prostate cell specific immune response.

15. The composition of claim 14, wherein prostate cell specific immune response is a PAP specific immune response.

16. The composition of claim 14 or 15, wherein the expression products of the genetic vaccine construct stimulate autoimmune prostatitis.

17. A recombinant vector for use in making the genetic vaccine construct according to any one of claims 1 to 11 comprising:

i) avipox virus vector nucleic acid sequences comprising sites for homologous recombination with an avipox virus vector;

ii) one or more promoters; and

iii) a sequence of nucleotides encoding a xenogeneic prostate specific polypeptide.

18. A recombinant vector for use in making the genetic vaccine construct according to any one of claims 2 to 11 comprising:

i) avipox virus vector nucleic acid sequences comprising sites for homologous recombination with an avipox virus vector;

ii) one or more promoters;

iii) a sequence of nucleotides encoding a xenogeneic prostate specific polypeptide; and

iv) a sequence of nucleotides encoding an immunostimulatory polypeptide.

19. A eukaryotic cell infected with a genetic vaccine construct according to any one of claims 1 to 11.

20. An antibody capable of acting as a marker for the genetic vaccine construct which antibody recognises epitopes uniquely formed in expression products of the genetic vaccine construct according to any one of claims 1 to 11.

21. A nucleic acid probe comprising a complementary form of a contiguous sequence of nucleotides of all or part of the genetic vaccine construct according to any one of claims 1 to 11 which specifically recognises said genetic vaccine construct under appropriate hybridisation conditions.

22. A method for stimulating or otherwise enhancing a prostate cell specific immune response in a subject comprising administration to the subject of an effective amount of a composition comprising a genetic vaccine construct comprising an avipox virus vector which incorporates and, on administration to a subject, expresses in a cell of said subject, a sequence of nucleotides encoding a xenogeneic prostate specific polypeptide or a derivative or analogue thereof, for a time and under conditions sufficient for expression products of said genetic vaccine construct to stimulate or otherwise enhance a prostate cell specific immune response, and wherein said avipox virus vector does not productively infect said subject.

23. A method for stimulating or otherwise enhancing a prostate cell specific immune response in a subject comprising administration to said subject of an effective amount of a composition comprising a genetic vaccine construct comprising an avipox virus vector which incorporates and, on administration to a subject, expresses in a cell of said subject, a sequence of nucleotides encoding a xenogeneic prostate specific polypeptide or a derivative or analogue thereof and

a sequence of nucleotides encoding an immunostimulatory polypeptide, for a time and under conditions sufficient for expression products of said genetic vaccine construct to stimulate or otherwise enhance a prostate cell specific immune response, and wherein said avipox virus vector does not productively infect said subject and a sequence of nucleotides encoding an immunostimulatory polypeptide.

24. A method for immunotherapy and/or immunoprophylaxis of prostate cancer comprising administration of an effective amount of a composition comprising a genetic vaccine construct comprising an avipox virus vector which incorporates and, on administration to a subject, expresses in a cell of said subject, a sequence of nucleotides encoding a xenogeneic prostate specific polypeptide or a derivative or analogue thereof, wherein said vector does not productively infect said subject, and wherein expression products of said vector stimulate a prostate cell specific immune response effective in the treatment and/or prophylaxis of prostate cancer.

25. A method for immunotherapy and/or immunoprophylaxis of prostate cancer comprising administration of an effective amount of a composition comprising a genetic vaccine construct comprising an avipox virus vector which incorporates and, on administration to a subject, expresses in a cell of said subject, a sequence of nucleotides encoding a xenogeneic prostate specific polypeptide or a derivative or analogue thereof, and a sequence of nucleotides encoding an immunostimulatory polypeptide, wherein said vector does not productively infect said subject, and wherein expression products of said vector stimulate a prostate cell specific immune response effective in the treatment and/or prophylaxis of prostate cancer.

26. The method of any one of claims 22 to 25, wherein the prostate specific polypeptide is a prostatic acid phosphatase or a derivative or analogue thereof and the prostate cell specific immune response is a PAP specific response.

27. The method of any one of claims 22 to 26, wherein the subject is a human.

28. The method claim 27, wherein the prostate specific polypeptide is rodent prostatic acid phosphatase.

29. The method of claim 28, wherein the rodent prostatic acid phosphatase is rat prostatic acid phosphatase.

30. The method of claim 23 or 25, wherein the immunostimulatory polypeptide is a cytokine.

31. The method of claim 29, wherein the cytokine is one or more of cytokines IL-2, IL-12, TNFα, IFNγ, IL-6, IL-4, IL-7 or GM-CSF.

32. The method of claim 31, wherein the cytokine is one or more of cytokines IL-2, IFNγ and/or IL-12.

33. The method of claim 32, wherein the cytokine is IL-2.

34. The method of any one of claims 22 to 33, wherein the avipox virus vector is a fowlpox virus vector.

35. Use of an avipox virus vector comprising a sequence of nucleotides encoding a xenogeneic prostate specific polypeptide or a derivative or analogue thereof in the manufacture of a medicament for use in stimulating or otherwise enhancing a prostate cell specific immune response in a mammalian subject.

36. Use of an avipox virus vector comprising a sequence of nucleotides encoding a xenogeneic prostate specific polypeptide or a derivative or analogue thereof and a sequence of nucleotides encoding an immunostimulatory polypeptide in the manufacture of a medicament for use in stimulating or otherwise enhancing a prostate cell specific immune response in a mammalian subject.

37. Use of an avipox virus vector comprising a sequence of nucleotides encoding a xenogeneic prostate specific polypeptide or a derivative or analogue thereof in the manufacture of a medicament for use in the immunotherapy and/or immunoprophylaxis of prostate cancer in a mammalian subject.

38. Use of an avipox virus vector comprising a sequence of nucleotides encoding a xenogeneic prostate specific polypeptide or a derivative or analogue thereof and a sequence of nucleotides encoding an immunostimulatory polypeptide in the manufacture of a medicament for use in the immunotherapy and/or immunoprophylaxis of prostate cancer in a mammalian subject.

39. The use of any one of claims 35 to 36, wherein the prostate specific polypeptide is a prostatic acid phosphatase or a derivative or analogue thereof and the prostate cell specific immune response is a PAP specific response.

40. The use of any one of claims 35 to 39, wherein the subject is a human.

41. The use claim 40, wherein the prostrate specific polypeptide is rodent prostatic acid phosphatase.

42. The use of claim 41, wherein the rodent prostatic acid phosphatase is rat prostatic acid phosphatase.

43. The use of claim 36 or 38, wherein the immunostimulatory polypeptide is a cytokine.

44. The use of claim 42, wherein the cytokine is one or more of cytokines IL-2, IL-12, TNFα, IFNγ, IL-6, IL-4, IL-7 or GM-CSF.

45. The use of claim 44, wherein the cytokine is one or more of cytokines IL-2, IFNγ and/or IL-12.

46. The use of claim 45, wherein the cytokine is IL-2.

47. The use of any one of claims 35 to 45, wherein the avipox virus vector is a fowlpox virus vector.